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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,630	12/17/2001	Francesco Casuscelli	217471US0	7565
7590		12/19/2006		
Peter I Bernstein				
Scully Scott Murphy & Presser				
400 Garden City Plaza				
Garden City, NY 11530				
			EXAMINER	
			EPPERSON, JON D	
			ART UNIT	PAPER NUMBER
			1639	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/19/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/015,630	Applicant(s) CASUSCELLI ET AL.	
	Examiner Jon D. Epperson	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-18 is/are rejected.
- 7) ☒ Claim(s) 19 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. The Response filed September 21, 2006 is acknowledged.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Status of the Claims

3. Claims 12-20 and 26 were pending. Applicants canceled claim 26 and amended claim 12. Therefore, claims 12-20 are currently pending and examined on the merits.

Withdrawn Objections/Rejections

4. The objection to claim 26 is hereby withdrawn in view of Applicants' cancellation of said claim. The Murthy et al. rejections under 35 U.S.C. § 102(b) are hereby withdrawn in view of Applicants' amendment to claim 12 adding "substituted phenyl" to the proviso language in the seventh line from the bottom. All other rejections and/or objections are maintains as set forth below.

Outstanding Objections and/or Rejections

Claim Rejections - 35 USC § 103

5. Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nawwar et al. (Nawwar et al. "Synthesis and Molluscicidal Activity of New Derivatives

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of 1-(Hydroxyl/substituted Phenyl)-3-arylpropenones” *Arch. Pharm. (Weinheim)* **1993**, 326, 831-836) (10/17/05 IDS) and Buchi (Buchi, J. “The Constitution-Effect Relationships from a New Viewpoint” *Deutsche Apotheker-Zeitung* **1966**, pages 1695-1700 (1-29 for English translation)).

For **claims 12-18**, Nawwar et al. (see entire document) disclose arylpropenones (e.g., see Nawwar et al., page 832, compound 9), which reads on the claimed invention. For example, compound 9a reads on the claimed invention when R_7 is $C(=O)NPh$ and R_{1-5} is hydrogen. For claim 26, it is noted that a preamble is generally not accorded any patentable weight where it merely recited the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Here, the “use as a medicament” statement occurs in the preamble and merely recites “the intended use of a structure” and thus is not afforded any patentable weight in accordance with cases like *In re Hirao* and *Kropa v. Robie*.

The prior art teaching of Nawwar et al. differ from the claimed invention as follows:

For **claims 12-18**, Nawwar et al. fail to disclose the requisite R_6 group. That is, Nawwar et al. only disclose R_6 = furan (e.g., see page 832, Scheme I, compound 9a).

However, Buchi teach the following limitations that are deficient in

Nawwar et al.:

For *claims 12-18*, Buchi (see entire documents) teach that “thiophene” and “pyrrole” are commonly substituted for “furan” for the purposes of modifying the biological activity of lead compounds e.g., furan → thiophene represents a “biosteric” substitution (e.g., see Buchi, page 3, Table 8).

It would have been prima facie obvious to one skilled in the art at the time the invention was made to substitute a thiophene or pyrrole ring for the furan ring disclosed by Nawwar et al. because Buchi explicitly state that this substitution is commonly made in the pharmaceutical arts as a result of the common chemical and/or physical properties that these two substituents display and that similar biological properties would result from such a substitution (e.g., see Buchi, page 3, Table 8; see also page 2, last paragraph, “molecules are isosteric if their peripheral electron layers can be seen as identical. IN this sense, the atoms and groups of atoms listed in table 8 are isosteric”; see also MPEP § 2144.09 “An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.” *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991)). One of skill in the art would have been motivated to make the substitution because, according to Buchi, “[b]y exchanging isosteric groups in active-ingredient molecules, it should be possible to produce

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effective analogs, since the electronic charge and physical/chemical properties of such a molecule should hardly change” (e.g., see Buchi, paragraph bridging pages 2 and 3). Finally, a person of skill in the art would reasonably expected to be successful because, according to Buchi, “the electronic charge and physical/chemical properties of such a molecule should hardly change” upon substitution and such changes have been applied to a wide variety of molecules (e.g., Buchi, paragraph bridging pages 2 and 3; see also page 4). See also MPEP § 2144.07 stating that it is *prima facie* obvious to substituted known equivalents for each other.

Response

6. Applicant’s arguments directed to the above 35 U.S.C. § 103(a) rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from its original version to more clearly address applicants’ newly amended and/or added claims and/or arguments.

Applicants argue, “The claims of the present application are directed to formula (I) which includes no lead atoms in its structure. As such, the basis of equivalence between thiophenes, pyrroles and furans, that is, the alleged equivalence between heterocyclics wherein the heterocyclic atoms are sulfur, nitrogen and oxygen, respectively, does not exist. The Buchi teaching of equivalence is limited to lead-containing compounds of which compounds within the contemplation of Claims 12-18 are free. The case law cited in the Official Action in support of the proposition that an

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obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make the claimed compound in the expectation that compounds similar in structure will have similar properties. That principle does not apply in the present case. The teaching of Buchi is strictly proscribed to lead-containing compounds. That teaching has absolutely no relevance to the claimed compound of the present application, the compound having the general formula (I), insofar as that compound contains no lead.” (e.g., see 9/21/06 Response, pages 232 and 233).

Applicants’ arguments are not commensurate in scope with the claims. For example, Applicants claim, “A hydroxyaryl-pyrazole derivative represented by formula (I) ...” (e.g., see claim 12), not “A hydroxylaryl-pyrazole derivative represented by formula (I) ... with the proviso that such a derivative may not be a lead compound.” That is, Applicants’ claims encompass all hydroxylaryl-pyrazole derivatives represented by formula (I) whether such compounds represent “lead” compounds or not. Thus, Applicants’ argument is moot. Furthermore, whether such a compound is “used” as a “lead” compound is immaterial because patentability is based on the structure of the compound not on the claimed intended use. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Accordingly, the 35 U.S.C. § 103(a) rejection cited above is hereby maintained.

New Rejections

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 12-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide support for the invention as now claimed. Claims 12 have been amended to recite, "when R₇ is CONH₂ or CSNH₂ and R₅ is H or CH₃, then R₆ is not H, CH₃, phenyl or substituted phenyl." However, the Examiner cannot find support for compounds of formula (I) wherein R₇ is C(=S/O)NH₂, R₆ is substituted phenyl, and R₁₋₄ is hydrogen. If applicant believes this rejection is in error, applicant must disclose where in the specification support for this amendment can be found in accordance with MPEP § 714.02.

Any negative limitation or exclusionary proviso must have a basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims (e.g., see *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977); see also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984); see also MPEP 2173.05(i)). Here, Applicants fail to positively recite in their specification compounds of formula (I) wherein R₇ is C(=S/O)NH₂, R₆ is substituted phenyl, and R₁₋₄ is hydrogen. Thus, these chemical substituents cannot be explicitly excluded in accordance with *In re Johnson* (see

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above). Furthermore, Applicants fail to reasonably provide any guidance and/or blaze marks that would otherwise lead a person of skill in the art to this particular group of compounds. Thus, Applicants' specification fails to provide an adequate basis for this negative limitation.

In addition, Applicants must provide, even in situations where an alternative is positively recited in the specification, a reason why their claimed invention is "clearly distinguishable" from the disclaimed species and/or subgenus (e.g., see *In re Langdon* 25 USPQ 415, 417 (CCPQ 1935) (holding a lack of written support for a negative limitation excepting nickel from an explicitly recited group of metals that compose the back coating of a glass mirror when no patentable reason was set forth in the specification that would otherwise distinguish the excluded nickel from other "equivalent" metals recited therein). Here, Applicants provide no patentable reason for distinguishing the compounds of formula (I) wherein R_7 is $C(=S/O)NH_2$, R_6 is substituted phenyl, and R_{1-4} is hydrogen from any of the other members of the currently claimed compounds. Thus, adequate support does not exist for the compounds of formula (I) wherein R_7 is $C(=S/O)NH_2$, R_6 is substituted phenyl, and R_{1-4} is hydrogen, even if, *assuming arguendo*, a positive recitation for these two substituents could be found in the specification, in accordance with *In re Langdon* (see above).

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kadu et al. (Kadu et al., "Studies in Co(II), Cu(II), and Ni(II) complexes with substituted pyrazoline and pyrazole at 0.1 ionic strength pH-metrically" *Asian Journal of Chemistry* 1999, 11(2), 420-423).

For *claims 12-16*, Kadu et al. (see entire document) disclose, for example, 4-benzoyl-3-(2-hydroxy-5-methylphenyl)-5-phenyl-1-(4 pyridinylcarbonyl)-1H-Pyrazole (e.g., see Kadu et al., page 423, Ligand-1, Registry Number 208660-42-8), which anticipates the claimed invention. For example, ligand-1 anticipates the claimed invention when R₇ is C(=O)-pyridine (i.e., COR₁₀ wherein R₁₀ = unsaturated heterocyclyl), R₆ is phenyl, R₅ is -C(=O)-Ph (i.e., "aryl C₁₋₆ alkyl" wherein the "C₁" methyl group is substituted with oxygen), R₃ = -CH₃ (i.e., C₁₋₆ alkyl), R_{1, 2, and 4} is hydrogen. The Examiner notes that Applicants' proviso language in claim 12 (e.g., "when R₇ is COR'₁₀ ...") is not implicated here because R₆ is not an optionally substituted phenyl but, rather, an optionally substituted "aryl C₁₋₆ alkyl."

Allowable Subject Matter

9. Claim 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

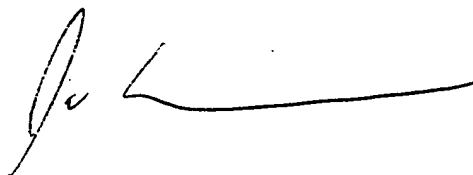
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
November 29, 2006

JON EPPERSON, PH.D.
PATENT EXAMINER

A handwritten signature in black ink, appearing to be 'J. Epperson', followed by a long horizontal line extending to the right.